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EFSA publishes report on 86/609

The European Food Standards Authority has published its report about certain aspects of the revision of Directive 86/609

The Animal Health and Welfare (AHAW) Panel of the European Food Safety Authority has produced a report on a number of issues raised in the preparations for drafting the revision of Directive 86/609 on the protection of laboratory animals. At the request of the European Commission, the panel, under the chairmanship of Professor David Morton, of Birmingham University, UK, looked at the following questions:

- The sentience of invertebrate species, and of fetal and embryonic forms of vertebrate species;
- In which cases animals used in experiments should be purpose-bred;
- Which are the most humane methods of euthanasia, and for which species.

In response to the first question, the report recommends that the following invertebrates should come under the scope of the revised directive, or at least be seriously considered for inclusion:

Cyclostomes (lampreys and hagfish)
Cephalopods (octopus, cuttlefish, squid)
Decapod crustaceans (lobsters, crabs, prawns etc)

In the case of fetal and embryonic forms of vertebrate animals, the panel recommended that "when a procedure is performed on a fetus that is likely to produce pain in the newborn or newly-hatched of that species, adequate anaesthesia and analgesia should be given provided that the agents used do not significantly increase the likelihood of fetal mortality. When the procedure might cause a lasting inflammatory response that persists post-natally, protection should be given against pain and suffering. A schedule of anaesthetics and analgesics that are suitable for use in pregnant animals and fetuses should be prepared."

Species listed in Annex 1 to Directive 86/609 are those that must be 'purpose-bred' when used in experiments, unless a specific exemption has been obtained. The criteria for inclusion in Annex 1 were not clearly defined, hence the reason for the Commission requesting an opinion from the AHAW committee. The report said that, ideally all laboratory animals should be purpose-bred, but this was clearly not possible in every case. They endorsed the species currently listed in Annex 1 and added "Genetically altered animals (of all species)

should be added to Annex I. The review of all the commonly used laboratory species has concluded that with the exception of quail (*Coturnix coturnix*) all the other species listed should continue to be purpose-bred and some further species should be added, namely: Chinese hamster (*Cricetus griseus*), Mongolian gerbils (*Meriones unguiculatus*), two *Xenopus* species (*X. laevis* and *X. tropicalis*) and two species of *Rana* (*R. temporaria* and *R. pipiens*).”

Nearly all animals are killed at the end of a research project, says the report, “and it is important that this is done humanely, i.e. causing as little suffering as possible for the animals concerned.” The report goes into considerable detail on the various technical ways of killing animals, particularly in the section on gaseous agents where there was much new data to be considered. In general, say the panel, they have adopted the recommendations given in the existing EU guidance on humane killing, with one exception. They concluded that, “Carbon dioxide should not be used as a sole agent in any euthanasia procedure unless the animal has first been rendered unconscious, i.e. it should be phased out as soon as possible.”

The full report is available on the EFSA web site at http://www.efsa.eu.int/science/ahaw/ahaw_opinions/1286_en.html

Swiss animal welfare referendum dropped

The Swiss animal protection association has withdrawn its referendum on animal welfare issues.

A broad-ranging initiative on animal welfare legislation which was introduced by Schweizer Tierschutz (STS), the main Swiss animal protection association, has now been withdrawn. The initiative contained provisions which would have banned animal experiments in the most severe category and required researchers to prove that they could not use non-animal methods instead, when applying for animal research licences.

The main reason for the withdrawal is the new animal protection law brought in by the government in December. However, say the STS, they are far from happy with the new law, and are now launching a call for another referendum to institute an ‘animal protection lawyer’. They will start gathering signatures in support of this initiative in April.

Under Swiss law, if the signatures of 100,000 voters can be collected within 18 months, the issue must go to the Parliament.

“At present, when an animal is maltreated or tortured by its owner, there is no-one to defend its interests” said Lukas Berger of the STS legal department. This can lead to the wrong judgement being made and to delays or even a total blocking of justice in a particular case, he said.

The STS did not deny that their decision was a strategic one. By withdrawing the call for a referendum and instituting another, they will be able to bring pressure on the Swiss government to include some of the issues that had been dropped from the animal protection legislation. It is not yet known if their new initiative will include anything relating to animal research.

Work restarts on Oxford animal facility

After a long suspension, Oxford University announced that building work has restarted on their new central animal facility

Work was halted in July 2004 after a series of threats were made to Montpellier, the contractors working on the buildings. Tactics included sending threatening letters to shareholders, attacking directors' cars and threatening to publish a list of investors on the internet.

In November 2004, a website listing the home addresses and phone numbers of university staff and government ministers was removed from the internet after protests by the university. The university was also successful in winning an injunction stopping protestors gathering outside and intimidating staff.

Understandably, the university is not saying who has taken over the work, nor will it discuss a date for its completion. University registrar David Holmes said: "The university remains firmly committed to the completion of this building which is part of an ongoing programme of replacing and updating existing laboratory space. The new biomedical research building will provide world-class facilities, reflecting the university's commitment to animal welfare and to scientific progress."

"Completing the project will be good for animal welfare, good for medical research and good for the treatment of life-threatening conditions all over the world."

🌀 New EU animal welfare action plan

Following the recent Commission-industry initiative on the 3 R's, the Commission launched a new action plan on animal welfare

In January, the European Commission announced that they were launching a "Community Action Plan on the Protection and Welfare of Animals 2006-2010." The objectives of the plan are to define EU animal welfare policy more clearly, to promote higher animal welfare standards and to support the Three R's approach to animal testing.

As with all such recent action plans, this one contained a number of broad and wide-ranging objectives and 'areas of action' as well as a list of specific actions. These specific actions included three relating to animal experimentation that were already part of the existing Commission programme: the Commission-industry partnership on alternatives to animal testing, the next report on the validation and regulatory acceptance of alternatives for cosmetic testing and the 'coordination of the Community position on the adoption' of the revised Appendix A of the Convention on animal experimentation.

The only new action was 'Preparatory work for the establishment of a European Centre-Laboratory for the protection and welfare of animals and the Validation of Alternative Testing Methods.' The exact meaning of this is unclear. It seems unlikely that the Commission has forgotten that it set up the European Centre for the Validation of Alternative Methods over a decade ago, so the most likely explanation is that this signals an expansion of EVAM's remit, to cover areas of animal welfare outside animal experimentation.

🌀 Further increase in UK animal research

The number of animal procedures conducted in the UK has risen for the fourth year in succession

The number of scientific procedures involving animals in the UK in 2004 was just over 2.85 million, according to the British Home Office, which collates and publishes statistics on animal use. This represented a rise of 2.3% over 2003, and was due to the large increase in the number of genetically modified mice and fish used for

research – a rise of almost 20%.

At the same time, the number of procedures using normal animals fell, said the Home Office, including a 12% decrease in primate use. Dogs, cats, horses and non-human primates together were used in less than half of one per cent of procedures.

Home Office Minister Andy Burnham said: "I am proud that the UK scientific community continues to carry out high quality research under standards of care and accommodation that are amongst the highest in the world. Animal research has led to advances in the treatment of many conditions such as asthma, peptic ulcers, schizophrenia and depression, polio, kidney disease and Parkinson's. Where there is no alternative available, we will continue to ensure that the balance between animal welfare and scientific advancement is maintained."

Proposed changes raise debate in Sweden

Swedish laws on the use of laboratory animals are being amended, raising concerns in the research community

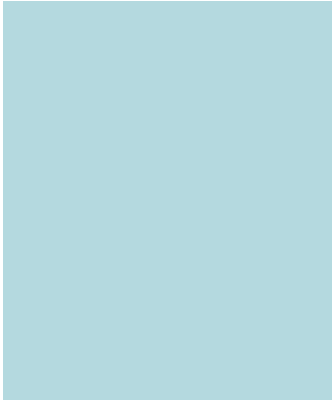
Sweden already has stringent animal welfare legislation, which includes research animals. However, says Karin Forsberg Nilsson, Deputy Secretary General at the Scientific Council for Medicine, if the proposed changes are accepted, the regulations are at risk of becoming less distinct and more complicated. Also, the changes mean more administrative work for researchers and for the ethical committees that review animal experiments.

The Swedish Animal Welfare Agency was assigned by the Government to review the Swedish animal welfare law. There are concerns about the way in which research is exempted from the legal ban on the use of "hormones and similar substances in animals for purposes other than to prevent, confirm, cure, and mitigate disease". The ban is actually aimed at animals in the agricultural and slaughtering sectors, and an exception to it is necessary to evaluate new drugs in animal experiments. The proposal for how the exception should be regulated have left researchers concerned. Referring to several points in the proposal, Karin Forsberg Nilsson says that the Agency has not addressed the concerns that she presented on behalf of the Swedish medical faculties.

Another controversial issue not addressed in the proposals from the Animal Welfare Agency concerns exceptions to a ban on breeding animals that might be subjected to pain or discomfort. The exception is necessary for the breeding of genetically modified animals, which is a key issue in biomedical research. Rather than have a clear proposal on how this would work in time for the revision of the law, the Animal Protection Agency has deferred a decision until the results of two research projects aimed at determining, the level of suffering of genetically modified animals.

Karin Forsberg Nilsson notes, however, that time is short. A new Animal Welfare Ordinance is supposed to come into force on March 15, 2006. Major problems will face biomedical research, she says, if the investigation is unfinished, but has resulted in final regulations concerning exceptions in breeding genetically modified animals.

The decision to review the legislation is based on a political agreement from March 2005 between the Swedish Government and its coalition parties. One part of the agreement involved starting a special investigation to determine if animal welfare organizations and the public should have the right to appeal decisions in the ethical



committees. In Sweden, there are seven such committees responsible for approving all animal experiments in universities, colleges, and industry. Today, only the researchers themselves can appeal decisions of the ethical committees.

When this article went to press, the investigation had not yet been commissioned, but the research community is very concerned that allowing animal protection groups to appeal the ethical committee decisions could give them a method of holding up the licences for research.

*This is a summary of an article by Carl-Magnus Hake in *Forskning and Medicin*.*